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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,110	08/07/2001	Kevin C. Carter	195/13921US03	9738

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McAndrews, Held & Malloy, Ltd.  
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EXAMINER

STEWART, ALVIN J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/924,110

Applicant(s)

CARTER ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 02/31/05
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1, 2, 4, 5, 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 4, 5, 31-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 02/31/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 31, 2005 has been entered.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on March 31, 2005 was filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Response to Arguments***

Applicant's arguments filed March 31, 2005 have been fully considered but they are not persuasive.

First the Examiner wants to thank, the Applicants, the Applicants' representative and the declarations of Mr. Brad J. Larson, M.D. and Mr. Raymond E. Olsen, for clarifying and describing their knowledge, the techniques used in the medical art for performing anterior cruciate ligament repair and for describing the differences between the Prior Art and the Applicants' invention.

The declaration under 37 CFR 1.132 filed March 31, 2005 is insufficient to overcome the rejection of claims 1, 2, 4, 8, 9 and 31-40 based upon the 35 U.S.C. 103 (a) rejection as set forth in the last Office action because: the Applicants' representative has not established a non-

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obviousness case, has failed to provide rebuttal evidence, has failed to provide experimental data showing that the combination of the anchoring system of the Beck, Jr. et al reference with the Campbell et al reference is not possible and has only shown the opinion of two experts with respect to the different techniques for performing anterior cruciate ligament repair. Although an opinion testimony is entitled to consideration and some weight the Examiner cannot give full weight to the experts' opinion without factual evidence supporting their arguments and having their opinions as the ultimate legal conclusion at issue.

The Applicants' representative remarks and the two declarations concentrate in disclosing two different techniques for performing anterior cruciate ligament repair between the Campbell et al reference and the Beck, Jr. et al reference. They also mention, but not in details, that one skill in the art would have no reason or motivation to put a groove on the bone block of the Campbell et al reference. However, the Examiner still believes that the combination between the Campbell et al reference and the Beck, Jr. et al reference is still proper. Campbell et al discloses almost all the structural limitations claimed in the application. However, it does not disclose a groove along the length of the bone blocks to accommodate a fixation screw.

The Examiner wants to point out that the invention is not related to the method of installing the implant or the technique used to perform a cruciate ligament repair. For the above reasons the Examiner has not given patentable weight to the method or technique used to perform a cruciate ligament repair. The only relationship between the Campbell et al reference and the Beck, Jr. et al reference is the simple installation of an interference screw to lock the ligament to the patient's bone.

Interference screws are well known in the art to be inserted between the bone plugs and the surface of the patients bone in order to provide a means of locking the ligament graft at a fixation site. Fixation screws have been used for years and for a purpose, the purpose of the screws is to connect the implant to the patient's bone. Therefore, the Examiner believes that the use of the interference screws of the Applicants' invention is not novel and has been on the market for years and the obviousness rejection is still proper. As evidence by the following prior art, some example are shown below:

- US 5,951,560;
- US 5,383,878;
- US 5,282,802

***Claim Rejections - 35 USC § 103***

Claims 1, 2, 4, 8, 9, 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al US patent 5,067,962 in view of Beck, Jr. et al US Patent 5,961,520.

Campbell et al discloses a xenograft replacement ligament comprising a bone-ligament-bone attachment with a naturally occurring attachment (see abstract and Fig. 3). The xenograft discloses a porcine or other large animals. Figure 3 discloses bone blocks shaped into a dowel. However, Campbell et al does not disclose a groove along the length of each bone block.

Beck, Jr. et al discloses an artificial ligament comprising an anchoring system made of bone (see col. 6, lines 36-39) and having a groove along the length (see Fig. 2, see element 17) for the purpose of inserting an attachment screw and attach the attachment system to the patient's bone.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the bone blocks of the Campbell et al reference with the longitudinal groove (see surface 17) of the Beck, Jr. et al reference in order to insert an attachment screw and attach the attachment system to the patient's bone.

Regarding claim 31, the shape of the Beck, Jr. et al reference can be used bi-directionally.

Regarding claim 32, it is an inherent characteristic of the process of preparing the xenograft material in order to be inserted in a human joint.

Regarding claim 33, see holes 25 & 26.

Regarding claim 34 & 37, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the shape of the Campbell et al reference by having a cylindrical shape or square cross section because Applicant has not disclosed that the cylindrical shape provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with taper shape of the Campbell et al reference because it will perform equally the same.

Therefore, it would have been an obvious matter of design choice to modify Campbell et al reference to obtain the invention as specified in claim 34.

Regarding claim 35, Campbell et al disclose the claimed invention except for a cylindrical dowel diameter of 9 through 12mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the diameter of the Campbell et al reference with the optimum value of 9 through 12mm, since it has been held that

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finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 38-40, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the Campbell et al reference with a first naturally occurring bone derived from a patella and a second naturally occurring bone derived from a tibia because Applicant has not disclosed that a first bone block derived from the patella and a second bone block derived from a tibia provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a donor animal ligament that is capable of having the size and strength of the patients injured ligament because it will be capable of withstanding the forces exerted in the patients knee joint.

Therefore, it would have been an obvious matter of design choice to modify the Campbell et al reference to obtain the invention as specified in claim 38.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 12, 2005.

**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
*A. Stewart*